

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON**

IN RE ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	Master File No. 2:12-MD-02327 MDL 2327
THIS DOCUMENT RELATES TO: WAVE 4 CASES LISTED IN MOTION EXHIBIT A	JOSEPH R. GOODWIN U.S. DISTRICT JUDGE

**DEFENDANTS' REPLY IN SUPPORT OF MOTION TO EXCLUDE
THE OPINIONS AND TESTIMONY OF DR. JIMMY W. MAYS, PH.D.**

Defendants Ethicon, Inc., Ethicon LLC, and Johnson & Johnson (collectively, “Ethicon”) submit this Reply in Support of their Motion to Exclude the Testimony and Opinions of Dr. Jimmy W. Mays, Ph.D. [Doc. 3642 (“Mot.”)] and Memorandum in Support [Doc. 3647 (“Defs.’ Mem.”)] (collectively, “Motion”). Plaintiffs’ Response to the Motion [Doc. 3751 (“Response”)] is primarily a copy of Plaintiffs’ Wave 3 Response [Doc. 2891]. Ethicon hereby adopts and incorporates by reference its Wave 3 Reply in Support of its Motion to Exclude the Testimony and Opinions of Jimmy Mays, Ph.D. [Doc. 3031]. In addition, Ethicon submits the following in reply:

Plaintiffs’ only new argument in its Wave 4 Response is to try to avoid the clear dictates of the Fourth Circuit’s decision in *Nease v. Ford Motor Co.*, 848 F.3d 219 (4th Cir. 2017). Plaintiffs argue that *Nease* is distinguishable because “Dr. Mays’ degradation opinions can be and have been verified, and the specific mechanisms of polypropylene degradation have been known for many decades and come from published, peer-reviewed, scientific literature.” Resp. at 7. The Court should reject these arguments.

Plaintiffs do not actually cite any support for their claim that Dr. Mays's degradation opinions have been tested. Instead, they just generally cite Dr. Mays's report. *See* Resp. at 7. Dr. Mays did not conduct any of his own testing. *See* Defs.' Mem. at 8–9. Instead, Plaintiffs appear to base their argument on Dr. Mays's reliance on scientific literature and on a handful of internal Ethicon documents. Thus, Plaintiffs' "testing" argument folds into their general argument that Dr. Mays's opinions were reliably based on the published literature and unpublished Ethicon testing.

As explained in Ethicon's Motion, neither of these sources provides a reliable basis for Dr. Mays's opinions. *See id.* at 9–15. Importantly, Plaintiffs do not cite any peer-reviewed testing for the specific hypothesis Dr. Mays seeks to offer here: that **Prolene** polypropylene mesh undergoes oxidative degradation *in vivo*. To the extent internal Ethicon documents addressed Prolene, those documents do not support Dr. Mays's conclusion that degradation actually occurs because there was no loss of molecular weight to confirm degradation. *See id.* at 13–15.

Further, these sources do not show that degradation of Prolene "is scientifically proven." Resp. at 7. Far from it, these sources show that there is substantial debate in the scientific community whether polypropylene, especially Prolene, is even susceptible to oxidative degradation under typical *in vivo* conditions. *See* Defs.' Mem. at 9–15. For example, in the Costello Single Patient Study, a Bard polypropylene mesh showed signs of degradation, while the Ethicon Proceed mesh (which consisted of Prolene mesh coated with oxidized cellulose) showed no signs of surface degradation. *Id.* at 11–12. Further, while the Ethicon documents showed some signs of cracking, there was no evidence of molecular weight loss, a crucial indicator of degradation. *See id.* at 13–15.

Even assuming that some of the literature Dr. Mays cites might support his degradation opinions, this would not be enough to show that Dr. Mays's theory has been adequately tested using reliable methodology. The only article cited that actually tested oxidative degradation of Prolene is the Mary paper, which was subject to serious methodological flaws. *Id.* at 12–13. Had Dr. Mays performed a test identical to the Mary article, using the same methodology, that testing would be subject to exclusion under *Daubert* due to lack of reliability. The fact that this same unreliable methodology was used in a published article does not negate these methodological flaws, and this unreliable article is not a substitute for reliable testing of Dr. Mays's degradation theory. Further, this unreliable methodology did not even confirm degradation through molecular weight testing or other means. *See id.* At best, the literature shows that more testing is necessary to determine whether Prolene is subject to *in vivo* oxidative degradation.

Applying the *Nease* analysis to Dr. Mays's degradation opinions should lead to the conclusion that these opinions are unreliable and inadmissible. Dr. Mays did not conduct his own testing, and his hypothesis that Prolene undergoes oxidative degradation *in vivo* has not been validated through reliable testing. Even construing the literature and unpublished Ethicon testing in the light most favorable to the Plaintiffs, these sources do not validate this hypothesis and did not reliably test it. Dr. Mays's "failure to test his hypothesis" that Prolene is subject to oxidative degradation *in vivo* "renders his opinions . . . unreliable" and inadmissible. *Nease*, 848 F. 3d at 232.

CONCLUSION

For all of these reasons, as well as those set forth in Ethicon's Motion, Ethicon respectfully requests that the Court grant its Motion to Exclude the Testimony of Dr. Jimmy Mays.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on May 4, 2017, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to CM/ECF participants registered to receive service in this MDL.

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